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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,422	10/07/2005	Vinod Chintamani Malshe	044.P001	6676

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EXAMINER	
HELM, CARALYNNE E	

ART UNIT	PAPER NUMBER
1615	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/552,422	MALSHE ET AL.	
	Examiner	Art Unit	
	CARALYNNE HELM	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 January 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,7,8,10-17 and 19-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,7,8,10-17 and 19-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2, 4, 7, 15, and 22-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 2, 4, 7, and 15 now each recite an approximate numerical range instead of a discrete numerical range as previously claimed. In each case, there specification does not provide written basis for the expansion of these ranges by indicating that applicants originally contemplated values outside of the originally recited range. In addition, the original disclosure as filed did not provide any general teachings that its recited numerical values were approximate. Therefore it is not clear that applicants had possession of the invention as currently claimed. This is a new matter rejection.

Claim 22 recites that the “poly(ethylene sebacate) is capable of releasing said water insoluble acid." There was no mention of any water insoluble acid in general or mention of any particular water insoluble acid in the disclosure at the time of filing.

Therefore it is not clear that applicants had possession of the invention as currently claimed. This is a new matter rejection.

Claim 23 recites that the “pharmaceutical composition comprises sebacic acid formed during hydrolysis of said poly(ethylene sebacate)." There was no mention of sebacic acid as an inherent result of hydrolysis of poly(ethylene sebacate) or discussion of sebacic acid being present in the pharmaceutical composition in the disclosure at the time of filing. Therefore it is not clear that applicants had possession of the invention as currently claimed. This is a new matter rejection.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 22 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 22 recites the limitation "said water insoluble-acid" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art

> are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The four factual inquires of Graham v. John Deere Co. have been fully considered and analyzed in the rejections that follow.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3, 11, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Penhasi (previously cited).

Penhasi teaches catheters, surgical mesh and film structures for their devices composed of a blend of elastomeric and non-elastomeric polymers along with a drug (see paragraphs 16, 22-24, 53, 58, and claim 10; instant claims 1, 11, 19). The catheters, surgical mesh and films are all capable of being implanted; therefore they meet the limitations of non-stent implants. In addition, Penhasi teaches drug being incorporated in the polymer matrix where, poly(ethylene sebacate) is taught as one of the envisioned non-elastomeric polymers (paragraph 35 line 33-34; instant claims 1 and 2). Anti-restenotic drugs are envisioned in the polymer blend and are well known to include anti-inflammatories, anti-proliferatives, anti-coagulants, as well as anti-platelets (see paragraph 46; instant claim 3).

Although Penhasi does not provide an explicit example where poly(ethylene sebacate) is the non-elastomeric polymer in the blend, it would have been obvious to one of ordinary skill in the art at the time of the invention to follow the explicit teachings of Penhasi to select poly(ethylene sebacate) as the non-elastomeric polymer for the drug/polymer blend and form it into a film, catheter or mesh as taught to yield a device with good mechanical integrity that will have the ability to retain its shape in expanded mode as taught (see claim 10). Therefore claims 1, 3, 11, and 19 are obvious over Penhasi.

Claims 2 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Penhasi as applied to claims 1, 3, 11, and 19 above, and further in view of Zhu et al.

(previously cited) as evidenced by Namboori et al. (Journal of Applied Polymer Science 1968 12:1999-2005).

Penhasi as evidenced by Namboori et al. makes obvious the invention of claim 1 where a pharmaceutical composition composed of poly(ethylene sebacate) and a pharmaceutically active agent is shaped as a non-stent implant or film. Penhasi does not explicitly teach the molecular weight of the poly(ethylene sebacate).

Zhu et al. teach that aliphatic polyesters are preferred among biodegradable polymers due to their better biodegradability properties and that this property depends upon their molecular weight (see paragraph 1 lines 5-8; instant claim 2). In addition, Zhu et al. also teach molecular weights that range from approximately 800 to approximately 20400 for degradable aliphatic polyesters (see tables 1 and 2).

Namboori et al. teaches that complex polyesters are susceptible to basic hydrolysis (see page 2000 paragraph 1). The depicted reaction scheme shows that base attacks a carbonyl carbon in the chain resulting in a carboxylic acid terminated fragment and an alcohol terminated fragment.

Since poly(ethylene sebacate) is an aliphatic polyester, it would have been obvious to select one with a molecular weight between 800 and 20,400, as taught by Zhu et al., because it was a known finite range of molecular weight preparations available at the time of the invention which would have had a reasonable expectation of success in the invention of Penhasi (obvious to try). Since 20,400 is explicitly recited and falls within the molecular weight range of instant claim 2, this combination of teachings renders obvious the limitations of this claim. Additionally, the examples of

Penhasi teach polymers with molecular weights of at least 2000 being utilized in the devices. Poly(ethylene sebacate) is water insoluble. Thus, if treated with base, hydrolysis of this polymer would yield some large oligomers that would also be water-insoluble. Since hydrolysis of the polyester would yield acid terminated fragments, these large water insoluble fragments can be classified as acids. Thus poly(ethylene sebacate) as envisioned by Penhasi would be capable of releasing water insoluble acid as require my instant claim 22. Therefore claims 2 and 22 are obvious over Penhasi in view of Zhu et al. as evidenced by Namboori et al.

Claims 1, 3-4, 8, 10, 12, 15, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burns et al. (previously cited).

The instant disclosure does not distinguish between the structure of nanoparticles, microparticles, and microcapsules, therefore they are interpreted to be the same absent additional limitations in the claim that distinguish them.

Burns et al. teach microspheres composed of polymers that are envisioned for biomedical applications (see abstract). The particles are sized from 0.5 microns to 20 microns, can be interpreted as microparticles, nanoparticles, and microcapsules, and are envisioned for sustained (controlled) release (see paragraphs 18 and 32; instant claims 12 and 15). Particles of this size would be capable of being injected and can be administered parenterally, transdermally, orally, and nasally (mucosal) (see paragraph 94; instant claims 8 and 17). Poly(ethylene sebacate) is taught as a polymer contemplated in the particles (see paragraph 34; instant claims 1). Burns et al. go on to

teach that bioactive agents included in the particles are present at 0.5% to 65% (see paragraph 39; instant claim 4). Particular bioactive agents contemplated include steroids, analgesics, anti-histamines (anti-allergic agents), and anti-cancer agents (see paragraph 89; instant claim 3). Additionally, Burns et al. teach that the particles can be incorporated within a gel (see paragraph 93; instant claim 10). Although the instant intended use is not explicitly envisioned, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The gel suspended microparticles of Burns et al. would be capable of being administered to a periodontal space and thereby meet the limitations of the recited intended use.

While Burns et al. do not provide an example where poly(ethylene sebacate) is the polymer in their microspheres, it would have been obvious to one of ordinary skill in the art at the time of the invention to follow their teachings and select this polymer for their bioactive containing microspheres because it is explicitly envisioned in this role by Burns et al. and would have had a reasonable expectation of success for biomedical applications as they envisioned. Therefore claims 1, 3-4, 8, 10, 12, 15, and 17 are obvious over Burns et al.

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Burns et al. as applied to claims 1, 3-4, 8, 10, 12, 15, and 17 above, and further in view of Yoshioka et al. (previously cited) and Hoshino et al. (previously cited).

Burns et al. make obvious nanoparticles composed of the linear aliphatic polyester, poly(ethylene sebacate), and a drug that are envisioned for controlled release of the drug (see instant claim 1). Burns et al. do not explicitly teach the presence of a lipase in the nanoparticles.

Yoshioka et al. teach the inclusion of an agent in a polymeric drug delivery system to hydrolyze the polymer and allow control of the degradation rate of the polymer and subsequent rate of drug release (see page 341 column 1-page 342 column 1 line 9 and page 346 column 2 paragraph 2).

Hoshino et al. teach that lipases were known to degrade a linear aliphatic polyester of the same form as the poly(ethylene sebacate) taught by Burns et al. (e.g. polybutylene succinate).

Since Burns et al. sought to provide controlled release from their nanoparticles (microspheres) and the incorporation of a degradation inducing agent in polymeric drug delivery systems was known to aid in controlling the release of drug, it would have been obvious to one of ordinary skill in the art at the time of the invention to include such a compound in the nanoparticles of Burns et al. Given that Hoshino et al. teach lipases as a degradation inducing agent for linear aliphatic polyesters of the same form as poly(ethylene sebacate), it would also have been obvious for this artisan to select a lipase to include in the microparticles of Burns et al. and this addition would have had a

reasonable expectation of success. Therefore claim 16 is obvious over Burns et al. in view of Yoshioka et al. and Hoshino et al.

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Burns et al. as applied to claims 1, 3-4, 8, 10, 12, 15, and 17 above, and further in view of Chang et al. (US PGPub No. 2004/0167203).

Burns et al. make obvious nanoparticles composed of the linear aliphatic polyester, poly(ethylene sebacate), and a drug that are envisioned for controlled release of the drug (see instant claim 1). These particles are envisioned for administration via routes that require mucosal transport of the drug (see paragraph 94). Burns et al. do not explicitly teach the presence of sebacic acid in the nanoparticles.

Chang et al. teach the inclusion of sebacic acid as an absorption enhancer for transmucosal transport of drugs (see paragraph 11-12, 15, and 17).

Since mucosal delivery pathways are envisioned for the composition of Burns et al., it would have been obvious to one of ordinary skill in the art at the time of the invention to include sebacic acid as an absorption enhancer as the application of the same technique to a similar device to yield the same improvement. Therefore claim 23 is obvious over Burns et al. in view of Chang et al.

Claims 1, 3-4, 8, 12-14, 17, and 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thompson et al. (previously cited) in view of Farachi et al. (previously cited)

The instant disclosure does not distinguish between the structure of nanoparticles, microparticles, and microcapsules, therefore they are interpreted to be the same absent additional limitations in the claim that distinguish them.

Thompson et al. teach a microparticle (microcapsules) preparation where a peptide bioactive is dispersed within a polyester matrix that is suitable for injection (see column 2 lines 21-26 and 37-38; instant claims 1, 3, 8, and 17). The bioactive agent is present at 5 to 25% in the polymer (see column 2 lines 23-25; instant claim 4). Thompson et al. teach the microparticles as having sustained (prolonged) release properties (see column 12 lines 62-65; instant claim 12). The polyester can be any polyester that biodegrades (see column 3 lines 59-61). Thompson et al. go on to teach the presence of a stabilizer in the preparation, where poly(vinyl alcohol) is explicitly exemplified (see column 5 lines 30-36; instant claims 13-14 and 20-21). The particles are prepared by dispersing the polyester, solubilized in an organic solvent, into an aqueous solution of poly(vinyl alcohol) and peptide (see example 1). The resulting oil-in-water emulsion is agitated and vacuum filtered to collect the particles (see example 1). "'[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.' In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)….The structure implied by the process steps should be considered when assessing the patentability of

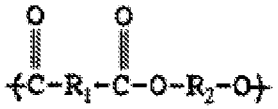
product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., In re Garnero, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979)" (see MPEP 2113). Therefore when no structure is implied, the product-by-process recitation does not add any limitations that affect patentability. Instant claims 13-14 and 20-21 recite a product-by-process that structurally requires a polymer core with drug coated that is coated with a stabilizer, where poly(ethylene sebacate) is located anywhere in the structure. While the claims are not limited to the method recited, Thompson et al. explicitly teach the limitations of the method and the microparticles it generates with the exception of poly(ethylene sebacate) as the polyester.

Farachi et al. teach that the polyalkylene sebacates of their invention are particularly good for their biodegradability (see column 2 lines 41-47 and 63-65). Farachi et al. also exemplify poly(ethylene sebacate) as a particular polyalkylene sebacate (see column 4 lines 57-59; instant claims 1 and 20).

As a polyester that was touted for its biodegradability, it would have been obvious to one of ordinary skill in the art at the time of the invention to select poly(ethylene sebacate) as taught by Farachi et al. for the polyester in the invention of Thompson et al. as the simple substitution of one known element for another with a predictable outcome. Therefore claims 1, 3-4, 8, 12-14, 17, and 20-21 are obvious over Thompson et al. in view of Farachi et al.

Claims 1 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duan et al. (previously cited) in view of Nakamura et al. (previously cited) and Burns et al.

Duan et al. teach a composition composed of particulate (granule) drug, a dispersing agent that is a compound comprising a chain of diol/diacid condensate and a propellant (see page 3 lines 1-8; instant claim 1). The dispersant compound is taught to have the form



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where R_1 and R_2 are organic moieties arising from the diacid and diol, respectively (see page 3 lines 13-22). The chain of diol/diacid condensate is taught to be made from any straight chain dicarboxylic acid and dihydric alcohol, where polyethylene glycol is envisioned as such an alcohol (see page 4 lines 7-8, 22, and 28; instant claim 1). Duan et al. go on to teach that the micronized particulate drug can be coated with the dispersant (see page 14 lines 24-29). Duan et al. do not explicitly teach sebacic acid as the diacid (e.g. poly(ethylene sebacate) as the dispersing aid).

Nakamura et al. teach poly(ethylene sebacate) as a dispersing aid (see column 7 line 41 and column 8 lines 1 and 5; instant claim 1).

Burns et al. teach microspheres composed of polymers that are envisioned for biomedical applications (see abstract). Poly(ethylene sebacate) is taught as a polymer

contemplated in the particles (see paragraph 34; instant claims 1). In addition, Burns et al. to teach that bioactive agents included in the particles (see paragraph 39).

Since poly(ethylene sebacate) was already known at the time of the invention to serve as a dispersing agent and to be safe for biomedical application and Duan et al. teach diol/diacid condensates prepared from any straight chain diacid and dihydric polyethylene glycol, it would have been obvious to one of ordinary skill in the art at the time of the invention to select poly(ethylene sebacate) as the diol/diacid condensate coating the particulate drug of Duan et al. as the simple substitution of one known element for another with a predictable outcome. "'[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.' In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)….The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., In re Garnero, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979)" (see MPEP 2113). Therefore when no structure is implied, the product-by-process recitation does not add any limitations that affect patentability. Instant claim 7 recites a product-by-process whose

structural limitations require, at most, a coating of poly(ethylene sebacate) on the surface of a drug containing granule. A granule is interpreted as a particle, thus the teaching of Duan et al. in view of Nakamura et al. and Burns et al. renders obvious a particular preparation of drug that is coated with poly(ethylene sebacate). Moreover whether applied as a coating on the particles directly or solubilized in a propellant, as taught, the dispersant forms a coating on the surface of the drug particles in the preparation taught by Duan et al. (see page 14 lines 12-29). Thus claims 1 and 7 are obvious over Duan et al. in view of Nakamura et al. and Burns et al.

Response to Arguments

Applicant's arguments filed January 3, 2011 have been considered but are unpersuasive.

Concerning each of the rejections made under 35 USC 103(a), applicants repeatedly argue that the references do not teach that poly(ethylene sebacate) is hydrolytically stable or that it is capable of releasing a water-insoluble acid. Neither of these limitations is recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Applicants also put these limitations forward as unexpected outcomes of the polymer that makes poly(ethylene sebacate) superior to poly(lactide acid) (PLA) or poly(glycolic acid) (PGA). No evidence is provided that demonstrates that poly(ethylene sebacate) has a hydrolytic stability that is unexpectedly superior to that of PGA or PLA as asserted. In

addition, applicants also do not support their assertion of the unexpected liberation of water insoluble acid from the degradation of poly(ethylene sebacate). Therefore applicants' claims of unexpected results are unpersuasive.

Rejection under 35 USC 103(a) over Penhasi:

Applicants argue that the selection of poly(ethylene sebacate) would not have been obvious for the structures taught by Penhasi because the examples only show PLA. The teachings of a prior art reference are not limited to its examples. Penhasi clearly sets forth polymers for the envisioned surgical articles and names poly(ethylene sebacate) as one of these polymers. Selection of this polymer by the artisan of ordinary skill in the art would require no more than following the explicit directive of Penhasi. In addition, Penhasi explicitly states that the invention is not limited to the particular embodiments of the invention that had been described (see paragraph 77).

Applicants also assert that poly(ethylene sebacate) has a lower polarity and greater solubility than PLA as well as a lower melting point and viscosity than both PLA and PGA which makes it superior for pharmaceutical compositions. These assertions do not overcome the rejection of record since none of these properties are required by the instant claims and the broad recitation of a pharmaceutical ingredient does not require their presence.

Rejection under 35 USC 103(a) over Burns et al.:

Applicants argue that the selection of poly(ethylene sebacate) would not have been obvious for the structures taught by Burns et al. because the examples do not show microspheres with this polymer. The teachings of a prior art reference are not limited to its examples. Burns et al. clearly set forth polymers forth the envisioned microspheres and names poly(ethylene sebacate) as one variety. Selection of this polymer by the artisan of ordinary skill in the art would require no more than following the explicit directive of Burns et al. In addition, Burns et al. explicitly state that the scope of the invention is not limited to the examples (see paragraph 113).

Rejection under 35 USC 103(a) over Burns et al. in view of Yoshioka et al. and Hoshino et al.:

Applicants argue that Yoshioka et al. do not teach the use of lipase in their study and Hoshino et al. shows degradation of PLA and not poly(ethylene sebacate). As the rejection notes, Hoshino et al. shows the ability of lipase to degrade a polyester that is a poly(alkylene diacid) which is the same form as poly(ethylene sebacate). Based upon this teaching the artisan of ordinary skill in the art would have expected that a lipase would also degrade poly(ethylene sebacate). Yoshioka et al. motivate the inclusion of a degradation aid in the particles of Burns et al. Therefore applicants' arguments concerning the teachings of Yoshioka et al. and PLA in Hoshino et al. are not sufficient to overcome the rejection.

Rejection under 35 USC 103(a) over Thompson et al. in view of Farachi et al.:

Applicants reiterate arguments that were addressed above; therefore this response is similarly reiterated.

Rejection under 35 USC 103(a) over Duan et al. in view of Nakamura et al. and Burns et al.:

Applicants reiterate arguments concerning unexpected results that were addressed above; therefore this response is similarly reiterated. Applicants also argue that the aerosol drug of Duan et al. is not a solid or a liquid; however, their aerosol includes microparticles which are the solid pharmaceutical delivery system, as instantly required.

Applicants reiterate arguments concerning unexpected results that were addressed above to address new claims 22 and 23; therefore this response is similarly reiterated.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CARALYNNE HELM whose telephone number is (571)270-3506. The examiner can normally be reached on Monday through Friday 9-5 (EDT).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on 571-272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Caralynne Helm/
Examiner, Art Unit 1615

/Juliet C Switzer/
Primary Examiner, Art Unit 1634